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AMENDMENT

### **REMARKS**

Claims 21-22, 26, 29, 47-55, 57, 66-67, and 96-115 are pending herein. By this Amendment, new Claims 110-115 are added. Support for the new claims is found in the specification at, *inter alia*, page 13, lines 19-23.

Applicants thank Examiner Webman for indicating that Claims 54 and 57 recite allowable subject matter. Applicants' representative called Examiner Webman to request clarification as to the pending claims. In particular, Claims 107-109 were added by the Amendment filed on September 9, 2003, but were not reflected in the current Office Action. In a November 4, 2003 telephone conference, Examiner Webman indicated that Claims 107-109 are also pending and rejected. No new matter is added by this Amendment.

#### **I. RESTRICTION AND ELECTION OF SPECIES REQUIREMENTS**

As the pending claims are allowable for the reasons described herein, search and examination must continue as to the non-elected species of encapsulants, such as enzymes and probiotics. Thus, withdrawn Claims 53, 98, and 100 have not been canceled.

#### **II. REJECTION UNDER 35 U.S.C. 103(a)**

Claims 21-22, 26, 29, 47-52, 55, 66-67, 96-97, 99, and 101-106 [sic: 101-109] were rejected under 35 U.S.C. 103(a) over U.S. Patent No. 5,262,167 (Vegesna et al.) in view of U.S. Patent No. 5,716,615 (Cavaliere Vesely et al.), U.S. Patent No. 3,925,343 (Hampton et al.), and U.S. Patent No. 3,762,931 (Craig et al.). This rejection is respectfully traversed.

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A. VEGESNA ET AL.

Vegesna et al. discloses a non-baked cholestyramine composition in which cholestyramine is in stable admixture with a carrier. The carrier is made up of a grain or flour, sugars, and starch binder, and may also contain an edible oil (Abstract). The composition comprises about 7 to about 20% by weight of one or more grain-based products (col. 2, lines 42-48). The non-baked cholestyramine composition is prepared in a very specific manner to ensure a low moisture content and to improve the taste and mouth-feel of the composition (col. 5, lines 3-21). The composition preferably has the consistency of coarse, chewable granules similar in size, appearance, and texture to that of wheat germ or granola (col. 2, lines 13-21; col. 5, lines 22-28). Vegesna et al. does not teach or suggest: (1) at least one plasticized matrix material comprising a durum ingredient; (2) an encapsulant that is at least substantially uniformly distributed in the at least one plasticized matrix material; or (3) a lactobacilli encapsulant.

B. CAVALIERE VESELY ET AL.

Cavaliere Vesely et al. does not overcome the deficiencies of Vegesna et al. Cavaliere Vesely et al. discloses a pharmaceutical composition containing several different bacteria including *Streptococcus thermophilus* and *Lactobacillus plantarum* or *Lactobacillus casei*. The composition may be useful in treating hypocholesterolemia (col. 1, lines 15-17).

Like Vegesna et al., Cavaliere Vesely et al. does not teach or suggest: (1) at least one plasticized matrix material comprising a durum ingredient; or (2) an encapsulant that is at least substantially uniformly distributed in the at least one plasticized matrix material. Further, there is no teaching, suggestion, or motivation to combine Cavaliere Vesely et al. and Vegesna et al. The Examiner asserts that it would have been obvious

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for one of ordinary skill to "add lactobacilli to the composition of Vegesna et al to achieve the beneficial effect of a second agent for treating high cholesterol" (Office Action art page 2). However, the Examiner has not set forth any facts supporting the assertion that the addition of a *lactobacillus* agent to a specific non-baked cholestyramine composition would be expected to have a beneficial effect.

It is axiomatic that the teachings of references can be combined only if there is some suggestion to do so. The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. Further, as noted in *In re Lee*, 61 USPQ2d 1430 (Fed. Cir. 2002), there is a need for factual specificity and thoroughness underlying any inquiry regarding the combination of references and such inquiry cannot "be resolved on subjective belief and unknown authority." This factual showing is essential to avoid the use of improper hindsight and the use of an inventor's own teachings against him. Applicants respectfully request the Examiner to show in the record where there is support for the assertion that adding the *lactobacilli* of Cavaliere Vesely et al. to the cholestyramine composition of Vegesna et al. would have been obvious for one of ordinary skill in the art. The cited references give no indication that the combination of lactobacillus and cholestyramine is desirable or even possible. The non-baked cholestyramine composition of Vegesna et al. is prepared in a specific manner to ensure a low moisture content and to improve the taste and mouth-feel of the composition, which had been a particular problem with prior cholestyramine compositions. There is no teaching or suggestion that *lactobacillus* could be simply added to such a process.

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C. HAMPTON ET AL. AND CRAIG ET AL.

Hampton et al. does not overcome the deficiencies of Vegesna et al. and Cavaliere Vesely et al. Hampton et al. discloses converting wheat gluten into agglomerates under conditions that do not denature the gluten so that the gluten can be dispersed in water to form a relatively stable dispersion (Abstract).

The Examiner cites Hampton et al. for teaching that wheat gluten is a known binder for pharmaceutical tablet formulations. Absent hindsight reconstruction, there is no reasoning given as to why one of ordinary skill in the art would substitute the acid hydrolyzed pregelatinized starch binder of Vegesna et al. with wheat gluten. Although such a substitution might be possible, "obvious to try" reasoning is not the correct standard of obviousness under 35 U.S.C. 103. Moreover, Hampton et al. does not teach or suggest: (1) at least one plasticized matrix material comprising a durum ingredient or (2) a lactobacilli encapsulant that is at least substantially uniformly distributed in the at least one plasticized matrix material.

Craig et al. does not overcome the deficiencies of Vegesna et al., Cavaliere Vesely et al., and Hampton et al. Craig et al. discloses a process for making macaroni (pasta) products including mixing and extruding a paste (Abstract). Conventional extrusion presses using 3,500 to 7,000 psi may be employed (col. 1, lines 60-65; col. 5, lines 30-35). Craig et al. also requires paste modifying agents such as whey solids and sulfhydryl reducing substances to improve mixing and extrusion characteristics in the presence of substantially reduced proportions of water (col. 3, lines 26-45).

The Examiner cites Craig et al. for disclosing that durum wheat is known as being high in gluten content. Craig et al. states that flour obtained from durum wheat is needed to make macaroni products under high pressure. See col. 1, lines. 13-25 and 31-39. There is no teaching or suggestion to substitute the durum wheat of Craig et al. for the

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pregelatinized starch binder in Vegesna et al. In fact, there is no reason why one of ordinary skill in the art would seek to use the durum wheat of a smooth, hard, glassy pasta or macaroni product as obtained in Craig et al. for the coarse, granola-like, chewable granules disclosed in Vegesna et al.

None of the cited references teaches or suggests the combination of: (1) at least one plasticized matrix material comprising a durum ingredient; (2) an encapsulant that is at least substantially uniformly distributed in the at least one plasticized matrix material; and (3) a lactobacilli encapsulant. Thus, it would not have been obvious for one of ordinary skill in the art to make the claimed encapsulated products in view of the combined teachings of Vegesna et al. in view of Cavaliere Vesely et al., Hampton et al., and Craig et al. Reconsideration and withdrawal of the rejection are respectfully requested.


### III. CONCLUSION

In light of the foregoing remarks, this application should be in condition for allowance, and early passage of this case to issue is respectfully requested. If there are any questions regarding this Amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application.

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Any shortages in fees should be charged to, or any overpayment in fees should be credited to, Deposit Account No. 501032 (Docket #BVL-105).

Respectfully submitted,



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